PATTERSON BELKNAP WEBB & TYLER LLP William F. Cavanaugh, Jr. (WC-3474)
Nicolas Commandeur (NC-4280)
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000

LINITED STATES DISTRICT COURT

Attorneys for Defendant Abbott Laboratories and Proposed-Intervenor Abbott Laboratories Vascular Enterprises, Inc.

SOUTHERN DISTRICT OF			
BIRMINGHAM ASSOCIA	ΓES LTD, Plaintiff,	x : :	Case No. 07 Civ. 11332 (SAS) ECF Case
v.		•	
ABBOTT LABORATORIE	S, Defendant.	: : :	
		X	

#### DECLARATION OF WILLIAM F. CAVANAUGH, JR.

WILLIAM F. CAVANAUGH, JR., hereby declares under penalty of perjury pursuant to 28 U.S.C. § 1746 at follows:

- 1. I am a member of the law firm of Patterson Belknap Webb & Tyler, LLP, counsel for Defendant Abbott Laboratories ("Abbott") and proposed-intervenor Abbott Laboratories Vascular Enterprises Inc. ("ALVE") in this litigation. I submit this declaration in support of Abbott's Motion to Compel Arbitration and to Stay or Dismiss this Litigation, and in support of ALVE's Motion to Intervene and to Compel Arbitration.
- 2. On December 17, 2007, Birmingham filed its complaint against Abbott in this action. A true and correct copy of the complaint is attached hereto as Exhibit A. Upon receipt of the lawsuit, I wrote to Birmingham's counsel on January 3, 2008 demanding that the

litigation be stayed or dismissed in favor of arbitration. A true and correct copy of this letter is attached hereto as Exhibit B. In a letter dated January 4, 2008 Birmingham's counsel denied that request. A true and correct copy of that letter is attached hereto as Exhibit C.

- 3. Also on January 3, on behalf of ALVE, I wrote to Birmingham and its counsel to provide notice of ALVE's desire to resolve the dispute regarding the issues raised in this lawsuit pursuant to the ADR provisions of the Funding Agreement. A true and correct copy of this letter is attached hereto as Exhibit D. Under the ADR procedures outlined in the Funding Agreement, ALVE's notice triggered a 28-day period for good faith negotiations.
- 4. Counsel for Birmingham responded on January 4 to ALVE's notice of dispute by claiming that the notice was deficient insofar as it did not identify the nature of the dispute with adequate specificity and that the issues raised in the Litigation were not, in fact, arbitrable. A true and correct copy of this letter is attached hereto as Exhibit E. At the same time, however, Birmingham provided its own notice of dispute under the ADR provisions of the Funding Agreement relating to ALVE's failure to make royalty and milestone payments to which Birmingham claims it is entitled. A true and correct copy of this notice of dispute is attached hereto as Exhibit F. Specifically, Birmingham alleges that the Xience Stent constitutes the Drug Eluting Stent 2d Generation under the Funding Agreement.
- 5. On behalf of ALVE, I responded to Birmingham's arbitration demand in a letter dated January 15, 2008. A true and correct copy of that letter is attached hereto as Exhibit G. In that letter, I explained that ALVE disputed Birmingham's allegations, but agreed that the dispute regarding the Xience stent should be resolved pursuant to the ADR provisions of the Funding Agreement. We also provided additional specificity regarding the nature of ALVE's dispute against Birmingham relating to the ZoMaxx Stent: namely, that ALVE sought through

ADR a determination that neither ALVE, nor its affiliates, including Abbott, violated any duty to Birmingham under the Funding Agreement by the termination of the ZoMaxx development program. In a letter dated January 18, 2008, Birmingham's counsel responded to ALVE's more specific demand by persisting in its view that the dispute regarding the ZoMaxx Stent was not arbitrable. A true and correct copy of this letter is attached hereto as Exhibit H.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Dated: January 28, 2008

New York, New York

•

**EXHIBIT A** 

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

JUDGE SCHEINDLIN

BIRMINGHAM ASSOCIATES LTD.

Plaintiff.

— against —

ABBOTT LABORATORIES,

Defendant.

672iv. CV) 11332

COMPLAINT AND JURY DEMAND

Birmingham Associates Ltd. ("Birmingham" or "Plaintiff"), by its attorneys,

Dechert LLP, for its complaint against defendant Abbott Laboratories Co. ("Abbott" or "The Complaint"), alleges as follows:

#### PRELIMINARY STATEMENT

1. This case arises from Abbott's failure to fulfill its written promise in a "Keep Well Agreement" to further the commercial interests and success of Abbott Laboratories Vascular Enterprises Limited ("ALVE"), a vehicle for Abbott's cardiovascular and endovascular products development in which Birmingham had invested in reliance on that agreement. Birmingham's investment, and other, similar infusions of investment funds, enabled Abbott to pursue the development and commercialization of new products. Unbeknownst to Birmingham, it also enabled Abbott to count the investors' funding as part of Abbott's own stated research and development expenditures and to reflect higher earnings-per-share in Abbott's publicly filed income statements. Birmingham supplied funds in exchange for the right, among others, to receive future royalty and other payments resulting from development and commercialization

programs in certain areas. One of these was a program to develop and commercialize the ZoMaxx<sup>TM</sup> Drug-Eluting Coronary Stent System (the "ZoMaxx Stent," or "ZoMaxx"). A "drug-eluting stent" is a mesh sleeve inserted into a blocked blood vessel to hold it open while releasing a drug from a coating on the stent-body to reduce the risk of the vessel's re-blocking.

was on a path to profitable commercialization. A competitor's drug-eluting stent, which used exactly the same drug and coating as the ZoMaxx Stent, had already received regulatory approval and was flourishing (and has since flourished) on the market. Nevertheless, Abbott, which had promised that its interests were aligned with Birmingham's and that the investment was an opportunity for Birmingham to partner with Abbott, terminated the development of the ZoMaxx Stent after it acquired the rights to another drug-eluting stent then in development — a stent as to which Abbott took the position that Birmingham was not entitled to any royalties or other payments. Far from furthering ALVE's commercial interests, Abbott chose to damage those interests. Abbott breached its obligations in the Keep Well Agreement, obligations expressly intended for the benefit of Birmingham. Abbott is liable to Birmingham for its breach.

#### **PARTIES**

- 3. Birmingham is a Cayman Islands corporation organized and existing under the laws of the Cayman Islands. Birmingham is managed by Elliott International Capital Advisors, Inc., a Delaware corporation with its principal place of business in New York City.
- 4. On information and belief, Abbott is an Illinois corporation with its principal place of business in Abbott Park, Illinois.

#### JURISDICTION AND VENUE

- 5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332, as Birmingham and Abbott are, respectively, citizens of a foreign state and a State, and the amount in controversy exceeds \$75,000.
- 6. Venue in this county is proper pursuant to 28 U.S.C. § 1391, as Abbott's contacts with this judicial district, considered as if it were a separate State, are sufficient to subject it to personal jurisdiction here and the cause of action herein alleged arises out of Abbott's transaction of business in New York.

#### STATEMENT OF THE CASE

## Birmingham's Investment in ALVE's Development and Commercialization of the ZoMaxx Stent and Other Products

- 7. Abbott is a global healthcare company actively engaged in the research and development of, among other products, cardiovascular and endovascular medical device products.
- 8. Upon information and belief, ALVE is an indirect, wholly-owned subsidiary of Abbott.
- 9. A group of investors (the "Investors"), including Birmingham, entered into a Research and Development Funding Agreement (the "Funding Agreement") with ALVE, dated as of May 2, 2005. The Funding Agreement, an agreement governed by and to be construed in accordance with New York law, was executed by ALVE with respect to Birmingham on June 6, 2005, and was executed by Birmingham on June 7, 2005.
- 10. Pursuant to the Funding Agreement under which ALVE had a commercial interest in the development and commercialization of ZoMaxx and other new

pharmaceutical products and devices — Birmingham and the other Investors supplied \$182.7 million to ALVE to fund such development and commercialization. Birmingham is responsible for \$60 million of this funding.

- 11. In exchange for providing ALVE with funds, Birmingham and the other Investors received, among other things, the right to future royalty and other payments resulting from the development and commercialization of the ZoMaxx Stent and other products.
- stent body, a small, layered stainless steel and tantalum mesh tube or scaffold that is inserted into a coronary artery to hold the artery open. The ZoMaxx Stent's stent body is called the TriMaxx<sup>TM</sup> stent platform ("TriMaxx"). *Second*, there is the drug compound eluted by the stent: ABT-578 (also known as zotarolimus). *Third*, there is the polymer-carrier coating on the stent body that holds the drug compound, and elutes it into the artery wall around the stent. In the ZoMaxx Stent, the coating is a phosphorylcholine ("PC") polymer coating, and, along with an additional topcoat of the PC coating, is called Pharmacoat<sup>TM</sup> Polymer Coating.
- 13. In addition to investing in the program to develop the ZoMaxx Stent, Birmingham and the other Investors agreed to fund a separate stent development program referred to as "Drug-Eluting Stent Next Generation" and "Drug-Eluting Stent 2<sup>nd</sup> Generation," and two other programs unrelated to coronary stents.

## Abbott's Commitment to Further the Interests and Success of ALVE for the Benefit of the Investors

14. The Keep Well Agreement, for which Abbott and ALVE were the nominal parties, was likewise entered into on May 2, 2005, and is governed by New York law. A true and correct copy of the Keep Well Agreement is attached as Exhibit A hereto.

- 15. Abbott's undertakings in the Keep Well Agreement were made for the benefit of Birmingham and the other Investors. Specifically, the Keep Well Agreement provides in Section 2(b) that "Abbott's obligations hereunder are intended for the benefit of the Investors" and in Section 8 that "the undertakings herein of Abbott are for the benefit of the Investors."
- 16. Birmingham invested in ALVE in reliance on the Keep Well Agreement and the commitments that Abbott made to the Investors therein.
- 17. In Section 1(c) of the Keep Well Agreement, Abbott undertook for the benefit of Birmingham and the other Investors to use commercially reasonable efforts, as defined therein, "to further the commercial interests and success of ALVE, including by providing research and development, clinical trial and sales and marketing support" for the ZoMaxx Stent and other products.
- 18. Section 2(a) of the Keep Well Agreement provides that Abbott's obligations to the Investors "shall be irrevocable and shall be absolute and unconditional general obligations, irrespective of any matter."
- Investors are intended beneficiaries and may sue Abbott directly. Specifically, Section 8 provides that Abbott's undertakings in the Agreement "are for the benefit of the Investors" and Section 2(b) provides that Abbott's obligations "are intended for the benefit of the Investors," "may be enforced by the Investors directly," and that Birmingham, as an Investor, may bring an "action or actions ... against Abbott ..." to enforce its rights.

#### Abbott's Termination of the ZoMaxx Stent

- 20. Abbott reported to Birmingham that in 2005 it had spent in excess of \$31 million of Birmingham's and the other Investors' funding dedicated to the development of the ZoMaxx Stent.
- 21. In or about January 2006, Abbott publicly announced that it had entered into an agreement to acquire Guidant's vascular business, including Guidant's drug eluting stent in development known as XIENCE or XIENCE V (the "Xience Stent," or "Xience"). Abbott completed its purchase of Guidant's vascular business on or about April 21, 2006.
- 22. In connection with the Guidant acquisition, Abbott represented publicly, as well as directly to Birmingham and the other Investors, that the Xience Stent and the ZoMaxx Stent would successfully coexist. For example, on or about April 21, 2006, Abbott announced in a press release and an SEC filing that "[t]he combined Abbott and Guidant business offers a broad line of leading coronary and endovascular products, a pre-eminent sales force, and global manufacturing operations, as well as state-of-the-art [research and development] organization, which is developing innovative technologies and devices such as [the Xience Stent] and [the ZoMaxx Stent]."
- 23. After the Guidant acquisition, Abbott continued to use Birmingham's and the other Investors' funds to support the development of the ZoMaxx Stent. Abbott reported to Birmingham that, from January to September 2006, it had spent \$27.9 million of Birmingham's and the other Investor's funds on the ZoMaxx Stent, including on clinical trials that were intended to support Abbott's applications for regulatory approval of the ZoMaxx Stent in Europe and the United States.

- 24. On September 5, 2006, Abbott publicly announced that the ZoMaxx Stent and the Xience Stent were "flagship" products for its vascular division.
- 25. Even so, on or about October 3, 2006, after Abbott had spent nearly \$60 million of the \$73.5 million of Birmingham's and the other Investors' money dedicated to the ZoMaxx Stent, Abbott publicly announced that it intended to terminate the development of the ZoMaxx Stent.
- 26. Specifically, Abbott announced that it "will not pursue commercialization of [the ZoMaxx Stent], and will instead focus its commercial, manufacturing, and clinical resources on [the Xience Stent]."
- 27. As a part of this announcement, Abbott publicly disparaged the ZoMaxx Stent by stating that the Xience Stent was a "significantly better product."
- 28. Abbott subsequently withdrew its support for, and ceased the clinical trials for and other development of, the ZoMaxx Stent, and foreclosed the possibility of its commercialization.
- 29. Abbott has taken the position that that Birmingham is not entitled to any payments in connection with the commercialization of the Xience Stent.

## Abbott Terminated a Commercially Viable Product

- 30. Though Abbott discontinued the development of the ZoMaxx Stent, the ZoMaxx Stent was a commercially viable product and was on a path to obtain the necessary regulatory approval for sale in Europe and the United States.
- 31. To be approved for sale in Europe, Abbott would have needed to obtain a "CE Mark" from the appropriate regulatory authority in the European Union. In the United

States, the ZoMaxx Stent would have needed the approval of the Food & Drug Administration (the "FDA"), a department within the Department of Health and Human Services.

- 32. When Abbott discontinued the development of the ZoMaxx Stent, it had already made a submission to the British Standards Institute (the "BSI"), the body responsible for determining whether the ZoMaxx Stent was qualified for a CE Mark, and Abbott had pursued significant clinical testing in preparation for its submission to the FDA.
- 33. Upon information and belief, the data submitted to the BSI derived from the "ZoMaxx IVUS Clinical Trial," a clinical trial that produced positive results but was limited in scope and size. Upon information and belief, on or about September 11, 2006, and in response to Abbott's limited submission to the BSI, Abbott received "negative advice" from the Medicines Evaluation Board ("MEB") in the Netherlands, an entity working in conjunction with the BSI because of the drug component, ABT-578, in the ZoMaxx Stent.
- 34. Upon information and belief, the negative advice reflected the MEB's determination that the limited submission made by Abbott did not provide a sufficient basis for the MEB to determine that the ZoMaxx Stent should be approved for sale in the European Union. The negative advice was not a substantial setback for the ZoMaxx Stent. It is common for the MEB to issue a negative advice in response to a product's first application for approval and for the product to be approved after subsequent discussion and resubmission. It is rare for the MEB to issue a "positive advice" in response to a product's first submission.
- 35. The prospects for the ZoMaxx Stent's receiving a CE Mark were particularly favorable given that both TriMaxx, the stent body underlying ZoMaxx, and a drug-eluting stent similar to ZoMaxx, called Endeavor (the "Endeavor Stent"), had already received a

CE Mark. Through a cross-license with Abbott, the Endeavor Stent includes the same drug compound, ABT-578, and PC polymer coating, as the ZoMaxx Stent. The Endeavor Stent received a CE Mark in or about July 2005, and had already been commercialized and captured a significant market share in Europe at the time ZoMaxx was terminated. More recently, in October 2007, a federal advisory panel in the United States unanimously recommended that the FDA approve Endeavor for sale in the U.S.

- 36. Despite these prospects, on information and belief, Abbott made no efforts to try to resolve any issues raised by the MEB's negative advice and resubmit the ZoMaxx Stent for a CE Mark. Moreover, on information and belief, Abbott made no efforts to support the application with the results from a second trial, the "ZoMaxx I Clinical Trial."
- 37. Instead, after years of development and with the ZoMaxx Stent's approval for sale in reach, Abbott hastily announced its decision to terminate the ZoMaxx development program and pursue development of Xience.
- 38. Upon information and belief, only after this announcement which mooted any benefits that could be gained from meeting with the MEB and precluded any prospects for regulatory approval did Abbott representatives meet with the MEB and present the ZoMaxx I Clinical Trial Data.
- 39. Upon information and belief, the ZoMaxx I trial results showed that, applying appropriate statistical techniques, the ZoMaxx Stent met it primary endpoint.

## Abbott's Termination of the ZoMaxx Stent Was In Derogation of the Commercial Interests and Success of ALVE

- 40. Abbott's termination of the program to develop and commercialize the ZoMaxx Stent precluded its approval for sale in the highly profitable market for drug-eluting stents.
- 41. The mere approval for sale of the ZoMaxx Stent would have resulted in "milestone payments" for Birmingham and the other Investors. If Abbott had not terminated the ZoMaxx development program and the ZoMaxx Stent had received a CE Mark, Birmingham would have been entitled to its pro rata share, nearly a third, of a \$10 million milestone payment. If the FDA approved ZoMaxx Stent for sale in the United States, Birmingham would have been entitled to a similar pro rata share of a \$25 million milestone payment.
- 42. On information and belief, if Abbott had not terminated the ZoMaxx Stent, the ZoMaxx Stent would have been commercialized in Europe, the United States, and elsewhere and would have captured a substantial share of the drug-eluting stent market.
- 43. On information and belief, the worldwide revenue for drug-eluting stents in 2006 was \$5.6 billion. When Abbott presented the investment opportunity to the Investors in 2005, it stated that the "base case" share for ZoMaxx would be 11 to 12 percent of this global market.
- 44. In March 2006, an industry analyst projected that that ZoMaxx would capture 9 percent of the worldwide drug-eluting stent market by 2009, including a 10 percent share in the United States. As late as August 2006, an industry analyst predicted that ZoMaxx would get 11 percent of the global drug-eluting stent market share by 2010.

- 45. Moreover, the Endeavor Stent captured approximately 15 percent of the European drug-eluting market within three months of commercialization. On information and belief, sales of the Endeavor Stent in Europe demonstrated the acceptance of the PC polymer and ABT-578 and built confidence among physicians in their safety and efficacy.
- 46. On information and belief, the ZoMaxx Stent could have been positioned in the market as a "safe" stent, as Medtronic positioned the Endeavor Stent, and physicians would have supported the ZoMaxx Stent it due to their view that it had safety advantages over the other drug-eluting stents, including the Xience Stent. Even in terminating the ZoMaxx Stent, Abbott acknowledged that there were no safety concerns with respect to the ZoMaxx Stent.
- 47. Upon information and belief, the reason for Abbott's hasty, premature abandonment of the ZoMaxx Stent was that it saw greater benefit to *Abbott* in focusing its commercialization efforts on the Xience Stent, as to which it sought to deny the Investors any benefit.
- 48. Abbott's decision to cease development of the ZoMaxx Stent was a decision made without regard for and in derogation of the interests of ALVE, Birmingham, and the other Investors. Instead of furthering the commercial interests and success of ALVE, for the benefit of the Investors, as it covenanted to do, Abbott pursued an alternative strategy at the direct expense of ALVE and Birmingham and other Investors.
- 49. This breach of the Keep Well Agreement has greatly harmed Birmingham, diminishing the return on its investment through, among other things, a loss of milestone and royalty payments.

50. Upon information and belief, Birmingham is the only remaining Investor in ALVE, as the other Investors agreed, in or about July 2007, to sell back their interest in ALVE.

## CAUSE OF ACTION

### (Breach of Contract)

- 51. Birmingham repeats and realleges paragraphs 1 through 50 as though each were fully set forth herein.
  - 52. The Keep Well Agreement is valid and binding.
- 53. Birmingham is an intended beneficiary of Abbott's obligations and undertakings under the Keep Well Agreement, and the Keep Well Agreement expressly provided that Birmingham may sue Abbott directly for any breaches thereof.
- 54. Abbott breached its contractual obligations to Birmingham under the Keep Well Agreement to further ALVE's commercial interests and success by terminating development of the ZoMaxx Stent and publicizing disparaging statements about the ZoMaxx Stent in derogation of the commercial interests and success of ALVE.
- 55. As a result of this breach, Birmingham has been damaged in an amount in excess of \$70 million, or such amount as may be determined at trial, plus interest at the statutory rate from the time of Abbott's initial breach.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court order:

A. That Abbott is liable to Birmingham in an amount to be determined at trial, plus applicable prejudgment and post-judgment interest; and

B. Such further relief as the Court deems just and proper.

### **JURY DEMAND**

Plaintiff hereby demands a trial by jury.

Dated:

New York, New York

December 17, 2007

DECHERT LLP

Bv

Robert A. Cohen Daniel C. Malone Ross L. Hirsch Eric C. Kirsch

30 Rockefeller Plaza New York, New York 10112 (212) 698-3500

Attorneys for Plaintiff

**EXHIBIT B** 

### Patterson Belknap Webb & Tyler ...

1133 Avenue of the Americas New York, NY 10036-6710 212.336.2000 fax 212.336.2222 www.pbwt.com

January 3, 2008

By Hand and E-mail

Robert A. Cohen, Esq. Dechert LLP 30 Rockefeller Plaza New York, NY 10112 William F. Cavanaugh, Jr. Partner (212) 336-2793 Oirect Fax (212) 336-2394 wfcavanaugh@pbwt.com

Re:

Birmingham Associates Ltd. v. Abbott Laboratories,

07 CV 11332(SAS) (SDNY)

Dear Robert:

We represent Abbott Laboratories ("Abbott") in the above-referenced case (the "Litigation"). The May 2, 2005 Research and Funding Agreement (the "Agreement") that your client, Birmingham Associates Ltd., entered with Abbott Laboratories Vascular Enterprises Limited ("ALVE") provides that any dispute relating to the parties' respective rights under the Agreement "shall be resolved by Alternative Dispute Resolution ('ADR') in accordance with the procedures set forth in Exhibit 15.6 [of the Agreement]." The issues raised in the complaint filed by your client in the Litigation clearly constitute a dispute to be arbitrated pursuant to the ADR provisions of the Agreement. We have been authorized by ALVE to notify your client of ALVE's intention to have the dispute, which was the subject matter of the Litigation, resolved pursuant to the ADR provisions of the Agreement. A copy of the letter triggering the ADR process is attached.

Accordingly, Abbott and ALVE request that your client agree to dismiss the present lawsuit and proceed with arbitration, or, alternatively, that your client consent to staying the litigation pending resolution of this dispute by ADR. Please let me know promptly whether your client consents to proceeding with resolving this matter by ADR and to dismissal or stay of the Litigation, or whether it will be necessary to seek judicial intervention to compel arbitration and to dismiss or stay the Litigation.

Nothing in this letter shall be construed as a waiver of any of Abbott's or ALVE's rights and remedies.

Very truly yours,

William F. Cavanaugh, Jr.

**EXHIBIT C** 



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DANIEL C. MALONE Partner

daniel.malone@dechert.com +1 212 698 3861 Direct

January 4, 2008

#### **VIA EMAIL & HAND DELIVERY**

William F. Cavanaugh, Jr.
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036-6710

Re: Birmingham Assocs. Ltd. v. Abbott Laboratories, 07 CV 11332 (SAS) (SDNY)

Dear Mr. Cavanaugh;

We have received your letter of January 3, 2008, to Robert A. Cohen, Esq. We disagree with your contention that the issues raised in the Complaint filed by Birmingham Associates Ltd. ("Birmingham") against Abbott Laboratories ("Abbott") are governed by the ADR clause in the Research and Funding Agreement dated May 2, 2005 (the "Funding Agreement"), between Birmingham and Abbott Laboratories Vascular Enterprises Limited ("ALVE"). The Complaint asserts a claim against Abbott for breach of a Keep Well Agreement dated May 2, 2005; it does not assert any claim against ALVE, let alone a claim against ALVE under the Funding Agreement. Accordingly, the claim at issue in the Complaint was properly asserted in the pending action, and our client does not agree to dismiss or stay that action.

We realize that, given the timing of your letter, our response may leave you with concerns with respect to your time for answer. We are, of course, willing to extend reasonable courtesies.

Very truly yours,

Daniel C. Malone

**EXHIBIT D** 

### Patterson Belknap Webb & Tyler ...

1133 Avenue of the Americas New York, NY 10036-6710 212.336.2000 fax 212.336.2222 www.pbwt.com

William F. Cavanaugh, Jr.

January 3, 2008

By Hand

Partner (212) 336-2793 Direct Fax (212) 336-2394 wfcavanaugh@pbwt.com Birmingham Associates, Ltd. c/o Elliott Int'l Capital Advisors, Inc.

Robert A. Cohen, Esq. Dechert LLP 30 Rockefeller Plaza New York, NY 10112

New York, NY 10019

712 Fifth Avenue, 35th Floor

#### Gentlemen:

We represent Abbot Laboratories Vascular Enterprises Limited ("ALVE"). ALVE has authorized us to provide Birmingham Associates Ltd. with notice, pursuant to Section 15.6 of the May 2, 2005 Research and Development Funding Agreement (the "Agreement"), of a dispute regarding the issues raised in the Complaint that you filed in Birmingham Associates Ltd. v. Abbot Laboratories, 07 CV 11332(SAS) (SDNY) and of ALVE's intention to have the dispute resolved in accordance with Section 15.6 and Exhibit 15.6 of the Agreement.

This letter shall also constitute notice of the commencement of the 28-day period for good-faith negotiation of this dispute pursuant to the terms of Exhibit 15.6 of the Agreement. Please advise me as soon as possible who Birmingham Associates Ltd. designates to serve as its representative for these negotiations.

ALVE and all of its Affiliates (as that term is defined in Section 1.1 of the Agreement), including, but not limited to Abbott Laboratories, expressly reserve all of their rights and remedies.

Very truly yours,

William F. Cavanaugh, Jr.

**EXHIBIT E** 



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DANIEL C. MALONE Partner

daniel.malone@dechert.com +1 212 698 3861 Direct

January 4, 2008

#### **VIA EMAIL & HAND DELIVERY**

William F. Cavanaugh, Jr.
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036-6710

Re: Birmingham Assocs. Ltd. v. Abbott Laboratories, 07 CV 11332 (SAS) (SDNY)

Dear Mr. Cavanaugh:

We have received your letter of January 3, 2008, to our client, Birmingham Associates, Ltd. ("Birmingham"), and Robert A. Cohen, Esq.. The letter was sent on behalf of Abbott Laboratories Vascular Enterprises, Ltd. ("ALVE"). You stated in that letter that ALVE was purporting to give notice of a "dispute regarding the issues raised in the Complaint that you filed in Birmingham Associates Ltd. v. Abbot[t] Laboratories, 07 CV 11332(SAS) (SDNY)" and of ALVE's intention to have that "dispute" resolved in accordance with Section 15.6 and Exhibit 15.6 of the Research and Funding Agreement dated May 2, 2005 (the "Funding Agreement"). Yet it is not at all clear from your letter what dispute, if any, ALVE believes exists under the Funding Agreement between ALVE and Birmingham that should be subject to good faith negotiation pursuant to Exhibit 15.6 of the Funding Agreement. The Complaint filed by Birmingham asserts a claim against Abbott Laboratories for breach of a Keep Well Agreement dated May 2, 2005; it does not assert any claim against ALVE, let alone a claim under the Funding Agreement. Given that your letter failed to identify any dispute between Birmingham and ALVE, or to identify any issues under the Funding Agreement that you believe should be subject to negotiation, Birmingham does not accept your letter as notice under Section 15.6 of the Funding Agreement, and it disputes that your letter commenced the 28-day period for good faith negotiations.

Please be advised, however, that Birmingham has separately provided ALVE with notice of a dispute under the Funding Agreement, which relates to ALVE's failure to make milestone and royalty payments to Birmingham in connection with the Xience<sup>TM</sup> V Everolimus Eluting Coronary Stent System. As a courtesy, I have included a copy of that notice.



William F. Cavanaugh, Jr. January 4, 2008 Page 2

Please feel free to contact me if you would like to discuss any of the foregoing.

Very truly yours,

Daniel C. Malone

Enclosure

**EXHIBIT F** 

# BIRMINGHAM ASSOCIATES LTD. C/O ELLIOTT MANAGEMENT CORPORATION 712 FIFTH AVENUE 35TH FLOOR NEW YORK, NY 10019

January 4, 2008

#### VIA FEDERAL EXPRESS

Abbott Laboratories Vascular Enterprises Ltd. Attn: Managing Director Arthur Cox Building Earlsfort Terrace Dublin 2 IRELAND

Re: Research and Development Funding Agreement dated May 2, 2005

Dear Sir or Madam:

We refer to the Research and Development Funding Agreement dated May 2, 2005 (the "Funding Agreement") by and among Abbott Laboratories Vascular Enterprises Ltd. ("ALVE") and various investors (the "Investors"), including Birmingham Associates Ltd. ("Birmingham"). We write pursuant to Section 15.6 and Exhibit 15.6 of the Funding Agreement to provide formal notice of a dispute relating to our respective rights and obligations under that Agreement, and to request good faith negotiations in an attempt to resolve that dispute.

The dispute concerns Birmingham's entitlement to milestone and royalty payments in connection with the development and sales of the Xience<sup>TM</sup> V Everolimus Eluting Coronary Stent System (the "Xience Stent," or "Xience"). Pursuant to the Funding Agreement, Birmingham invested in the drug-eluting stent program of ALVE, which was defined to encompass all drug-eluting stents developed and sold by ALVE and its affiliates, including its parent company, Abbott Laboratories ("Abbott"), meeting certain specified criteria. Despite the fact that the Xience Stent meets those criteria, and was developed by Abbott during the term of the Funding Agreement, ALVE has denied that Birmingham is entitled to any payments on account of sales of the Xience Stent. ALVE has asserted that the Xience Stent was somehow outside the scope of the Funding Agreement, suggesting that it was part of a competing drug-eluting stent program, which was within the Abbott pipeline but off-limits to Investors. For the reasons explained below, Birmingham considers this position untenable, and seeks to recover the amounts due to it.

#### The Funding Agreement and Its Background

The Funding Agreement resulted from an effort by ALVE and its affiliates to obtain funding for their development of drug-eluting stents and other medical devices. During the discussions leading up to the signing of the Funding Agreement, it was initially contemplated that Abbott would be the Investors' contractual counterparty, and Abbott represented to prospective investors that the funding was intended to supplement the resources available to Abbott's Vascular Division and its affiliates for these development efforts, and that Investors would benefit from the expenditures and acquisitions made by Abbott and its affiliates relating to such devices. Abbott explained that it was following a "builders strategy" to develop its medical device pipeline, and emphasized that it had already invested large amounts in acquiring drugeluting stents and technology associated with them. Moreover, the investment was presented as a unique opportunity to partner with Abbott, and to benefit from Abbott's global development and

commercialization capabilities. Abbott represented further that Abbott's interests were aligned with those of the Investors with regard to drug-eluting stents. Although ALVE ultimately replaced Abbott as the Investors' contractual counterparty, and although Abbott is not and has never been a party to the Funding Agreement, ALVE warranted in the Funding Agreement that the representations that Abbott had made to the Investors were true, and Birmingham reasonably continued to expect that its investment would benefit from all drug-eluting stents and related technology within the Abbott pipeline. There was certainly never any suggestion that, during the term of the Funding Agreement, Abbott would pursue the development of any competing drug-eluting stents that would be outside the scope of the Funding Agreement.

Birmingham entered into the Funding Agreement with ALVE in reliance on the foregoing representations, among other things. Several Investors signed the Funding Agreement with ALVE on or about May 2, 2005, contributing \$117 million of what was defined in the Funding Agreement as "Development Funding." Subsequently, on or about June 7, 2005, Birmingham and several other Investors likewise entered into the Funding Agreement with ALVE, raising the Development Funding to its final total of \$182.7 million. Birmingham is responsible for \$60 million of the Development Funding.

In exchange for the Development Funding, Investors have the right, among others, to milestone payments and royalties based on net sales of certain medical devices to be developed by ALVE and its affiliates and licensees, following regulatory approval. These devices included two drug-eluting stents to be developed under separate programs. One program was to develop a stent that was specifically identified (the "ZoMaxx Stent," or "ZoMaxx"), the development of which was already well advanced at the time the Funding Agreement was signed, and the other was to develop a stent that was defined generally as the next drug-eluting stent commercialized from the drug-eluting stent program of ALVE and its affiliates, in which the Investors' funds were utilized, following ZoMaxx (the "2" Generation Stent"). While it was contemplated at the outset that the 2<sup>nd</sup> Generation Stent program would focus on developing a stent that would combine the drug included in ZoMaxx, ABT-578, with another drug, that term was defined broadly, because it was impossible to predict what the 2<sup>nd</sup> Generation Stent would be. The definition included any drug-eluting stent next commercialized, in which the Investors' funding was utilized, following ZoMaxx, including a stent that used a "new drug other than ABT-578," "new stent materials." or "new polymers." (Section 1.11.) Moreover, the Funding Agreement required ALVE, in pursuing any parallel programs to develop a potential 2nd Generation Stent, to spread the Investors' funding across all the programs. (Article 3.)

### The Acquisition of the Xience Stent as Part of Abbott's Builders Strategy

Following the conclusion of the Funding Agreement, Abbott's pursuit of its "builders strategy" led to an agreement with Boston Scientific Corporation ("BSC") in January 2006 to acquire the vascular intervention and endovascular solutions businesses of Guidant Corporation ("Guidant"). In buying these businesses, Abbott acquired a number of vascular products that were then under development, including the Xience Stent. As a drug-eluting stent, Xience had the potential to meet the Funding Agreement's definition of a 2<sup>nd</sup> Generation Stent; it simply had to be the next one developed by ALVE or its affiliates to be approved and sold commercially. At the time of the Guidant acquisition, ALVE assured Investors that the transaction would operate to their benefit, by making available a wide range of new technology relating to stents and other medical devices.

For a time after the acquisition, ALVE affiliates developed ZoMaxx and Xience concurrently, as well as other stents that, like Xience, would meet the Funding Agreement's definition of a 2<sup>nd</sup> Generation Stent if they were the next sold commercially. (We understand that Abbott expended substantial funds in

developing Xience during this period, ranging from approximately \$16 million to \$33 million per month, as multiple clinical trials were under way.) Ultimately, however, in October 2006, Abbott announced that it was terminating the development of ZoMaxx, on which it had spent nearly \$60 million of Investor funds, and that it would instead focus on Xience and bring Xience to market in Europe.

Since its commercial launch in Europe, the Xience Stent has generated considerable net sales, including net sales arising from both the version marketed directly by Abbott and its affiliates and a private-label version, called PROMUS, marketed by BSC as an Abbott licensee.

### The Dispute Under the Funding Agreement

When the Xience Stent reached the market, it became the 2<sup>nd</sup> Generation Stent within the meaning of the Funding Agreement, and Birmingham became entitled to milestone and royalty payments. Birmingham and its affiliates have repeatedly brought this to the attention of ALVE. Yet ALVE has disputed Birmingham's entitlement to any such payments. ALVE has taken the position that Abbott's interests were not aligned with the Investors' after all, and that the Xience Stent – although a product of Abbott's builder strategy, hailed in comments to the public as a "next generation" or "second generation" stent, and the subject of substantial development efforts by ALVE affiliates during the term of the Funding Agreement – was somehow outside the scope of the Funding Agreement. The position of ALVE in this regard is all the more flawed given that the Funding Agreement required ALVE to spread Development Funding across all 2<sup>nd</sup> Generation programs, and in no way authorized ALVE to operate any independent, competing stent programs. (Indeed, ALVE would have been precluded by the implied covenant of good faith and fair dealing inherent in the Funding Agreement from treating a competing stent as outside the scope of the Funding Agreement even if the Agreement had not required ALVE to spread Development Funding across all 2<sup>nd</sup> Generation stents under development.)

And while ALVE has announced that it has elected to treat another version of the Xience Stent — which may or may not ever reach the market — as the 2<sup>nd</sup> Generation Stent within the meaning of the Funding Agreement, the Agreement gave ALVE no discretion to determine which drug-cluting stent commercialized from the Abbott pipeline would be the 2<sup>nd</sup> Generation Stent. ALVE may well prefer to use Investor funds to support the development of a Xience-based stent as to which the obligation to make milestone and royalty payments is remote, but such a preference cannot provide a basis for denying Birmingham the milestone and royalty payments with respect to the Xience Stent that are rightfully due.

#### Request for Negotiations

Birmingham hereby requests that ALVE enter into good faith negotiations in an effort to resolve this dispute, as required by Exhibit 15.6 to the Funding Agreement. As set forth in that Exhibit, these negotiations should take place between our respective presidents or their designees within 28 days after the receipt of this notice. It is our hope that this matter will be resolved through negotiation. If it is not, however, Birmingham is prepared to invoke the alternative dispute resolution mechanism set forth in Exhibit 15.16 to enforce its rights under the Funding Agreement, including, but not limited to, its right to the milestone and royalty payments due on Xience (including its private-label version), plus interest on payments that are past due, as well as Birmingham's right to royalty reports and other accounting measures required under Article 6 of the Funding Agreement.

We would propose that we block out two days for the required negotiations, and that these discussions take place at the offices of our lawyers, Dechert LLP, at 30 Rockefeller Plaza in New York, where a joint

conference room and separate break-out rooms for each party can be made available. If additional meetings should prove necessary thereafter, we would be willing to meet you at a place of your choosing. Please let us know if you are amenable to these proposals.

If you would like to contact me by telephone to discuss any of the foregoing, I may be reached at 212-974-6000.

Yours incerely,

Elliot Greenberg

cc: President, Abbott Vascular Devices General Counsel, Abbott Laboratories

Daniel C. Malone, Esq.

**EXHIBIT G** 

### Patterson Belknap Webb & Tyler ...

1133 Avenue of the Americas New York, NY 10036-6710 212.336.2000 fax 212.336.2222 www.pbwt.com

January 15, 2008

William F. Cavanaugh, Jr. Partner (212) 336-2793 Direct Fax (212) 336-2394 wfcavanaugh@pbwt.com

**BY HAND** 

Mr. Elliot Greenberg Birmingham Associates Ltd. c/o Elliott Management Corporation 712 Fifth Avenue, 35<sup>th</sup> Floor New York, NY 10019

Daniel C. Malone, Esq. Dechert LLP 30 Rockefeller Plaza New York, NY 10112

Gentlemen:

Abbott Laboratories Vascular Enterprises Limited ("ALVE") has asked that I respond on its behalf to your January 4 letter. First, ALVE disagrees with your contention that you are entitled to any milestone or royalty payments under the May 2, 2005 Research and Development Funding Agreement (the "Funding Agreement") relating to the development of the Xience<sup>TM</sup> V Everolimus Eluting Coronary Stent System (the "Xience Stent"). ALVE agrees that the ADR provisions of the Funding Agreement are the appropriate mechanism for resolving this dispute. Second, as I indicated in my January 3, 2008 letter (the "January 3 Letter") (a copy of which is attached), we dispute the issues raised in the complaint that you filed in <u>Birmingham Associates Ltd. v. Abbott Laboratories</u>, 07 CV 11332 (SAS) (SDNY) (the "Litigation"). This dispute should also be resolved pursuant to the ADR provisions of the Funding Agreement.

### <u>Dispute Regarding Entitlement to Royalties or</u> <u>Other Payments Relating to Xience Stent</u>

Birmingham Associates ("Birmingham") is not entitled to any payments relating to the Xience Stent because the Xience Stent is not covered by the Funding Agreement. The Xience Stent does not, as you contend, constitute a "Drug Eluting Stent  $-2^{nd}$  Generation" under the terms of the Funding Agreement. Section 1.11 provides that the  $2^{nd}$  Generation Stent is one that is "commercialized from the DES Program in which Development Funding is utilized." The Xience Stent was not commercialized from the DES Program, and no Development Funding was used to support it.

Mr. Elliot Greenberg Daniel C. Malone, Esq. January 15, 2008 Page 2

#### <u>Dispute Regarding the Discontinuance of the</u> <u>ZoMaxx Stent Development</u>

As I indicated in the January 3 Letter, ALVE also has a dispute with Birmingham regarding the issues raised in the Litigation. Birmingham's counsel has responded that (i) the January 3 Letter does not set forth with adequate specificity the nature of the dispute, and (ii) the issues implicated in the Litigation cannot be arbitrated. Both assertions are wrong.

The January 3 Letter explained that ALVE has a dispute with respect to the matters raised in the complaint you filed in the Litigation. Because Birmingham and its attorneys drafted the complaint, you presumably have a firm understanding of the nature of the dispute asserted in it. Lest there be any doubt, ALVE disputes the contention that ALVE or any of its Affiliates (as that term is defined in Section 1.1 of the Funding Agreement), including Abbott Laboratories ("Abbott"), violated any duties to Birmingham based on the decision to discontinue the development of the ZoMaxx Stent. Under the Funding Agreement, ALVE and Abbott had the right to discontinue the development of the ZoMaxx Stent. ALVE therefore wishes to obtain a determination through the ADR procedures set forth in the Funding Agreement that neither ALVE, nor any of its Affiliates, including Abbott, breached any duty to Birmingham Associates based upon the determination to discontinue its program to commercialize the ZoMaxx Stent.

This dispute is clearly arbitrable. Birmingham's efforts to couch the Litigation as a limited claim against Abbott under the May 2, 2005 Keep Well Agreement — and having nothing to do with ALVE or the Funding Agreement — is disingenuous at best. Abbott's obligations to Birmingham under the Keep Well Agreement, if any, arise solely from the Funding Agreement. The Litigation is an attempt to circumvent having this dispute resolved by ADR under the Funding Agreement and will now lead to needless motion practice. This is a tactic that courts in analogous situations have routinely rejected, as we will now apparently be compelled to demonstrate to the Court in New York. Should Birmingham wish to reconsider this needless waste of time and resources, please let us know promptly. Otherwise, we will proceed with filing a motion to dismiss or stay the litigation as well as a request that the Court permit us to recover the cost of such relief.

Mr. Elliot Greenberg Daniel C. Malone, Esq. January 15, 2008 Page 3

#### **Good Faith Negotiations**

By virtue of the parties' respective ADR notices, the 28-day period for negotiations is unquestionably running. If Birmingham is interested in having a discussion in an attempt to resolve the disputes, please contact me. If not, please advise whether Birmingham is prepared to waive the negotiation time period so that we can move on to the next phase of the ADR.

Sincerely,

William F. Cavanaugh, Jr.

## Patterson Belknap Webb & Tyler ...

1133 Avenue of the Americas New York, NY 10036-6710 212.336.2000 fax 212.336.2222 www.pbwt.com

January 3, 2008

By Hand

Birmingham Associates, Ltd. c/o Elliott Int'l Capital Advisors, Inc. 712 Fifth Avenue, 35<sup>th</sup> Floor New York, NY 10019

Robert A. Cohen, Esq. Dechert LLP 30 Rockefeller Plaza New York, NY 10112 William F. Cavanaugh, Jr. Partner (212) 336-2793 Direct Fax (212) 336-2394 wfcevanaugh@pbwt.com

#### Gentlemen:

We represent Abbot Laboratories Vascular Enterprises Limited ("ALVE"). ALVE has authorized us to provide Birmingham Associates Ltd. with notice, pursuant to Section 15.6 of the May 2, 2005 Research and Development Funding Agreement (the "Agreement"), of a dispute regarding the issues raised in the Complaint that you filed in *Birmingham Associates Ltd.* v. Abbot Laboratories, 07 CV 11332(SAS) (SDNY) and of ALVE's intention to have the dispute resolved in accordance with Section 15.6 and Exhibit 15.6 of the Agreement.

This letter shall also constitute notice of the commencement of the 28-day period for good-faith negotiation of this dispute pursuant to the terms of Exhibit 15.6 of the Agreement. Please advise me as soon as possible who Birmingham Associates Ltd. designates to serve as its representative for these negotiations.

ALVE and all of its Affiliates (as that term is defined in Section 1.1 of the Agreement), including, but not limited to Abbott Laboratories, expressly reserve all of their rights and remedies.

Very truly yours,

William F. Cavanaugh, Jr.

**EXHIBIT H** 



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DANIEL C. MALONE
Partner

daniel.malone@dechert.com +1 212 698 3861 Direct

January 18, 2008

#### **VIA EMAIL & HAND DELIVERY**

William F. Cavanaugh, Jr.
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036-6710

Dear Mr. Cavanaugh:

I have your letter of January 15, on behalf of Abbott Laboratories Vascular Enterprises, Ltd. ("ALVE"), to Mr. Elliott Greenberg, of our client, Birmingham Associates, Ltd. ("Birmingham"), and me. You have previously stated that your firm represents Abbott Laboratories ("Abbott"), defendant in *Birmingham Assocs. Ltd. v. Abbott Laboratories*, 07 CV 11332 (SAS) (SDNY).

Your letter appears to constitute a single response to two letters I sent on January 4 concerning the separate disputes that have arisen under the Keep Well Agreement (between Birmingham and Abbott) and under the Funding Agreement (between Birmingham and ALVE) concerning the ZoMaxx Stent and Xience Stent, respectively. This letter presents Birmingham's response with respect to these various disputes.

#### Birmingham's Dispute with ALVE Under the Funding Agreement Concerning Xience

While Birmingham strongly disagrees with the position you set out, if briefly, in your January 15 letter, the existence of a dispute at least is clear. In your letter, you asked if Birmingham is interested in having a discussion with respect to "the disputes," which I presume included the dispute with respect to this claim. Birmingham takes seriously its commitment to attempt to reach resolution of the dispute through good-faith negotiations and, in its letter to ALVE of January 4, proposed a procedure for such negotiations. Please have ALVE communicate a response to that proposal to Birmingham. Alternatively, please provide Abbott's response to me. I ask that you not, either in this connection or otherwise, communicate directly with our client.

## Birmingham's Complaint Against Abbott Under the Keep Well Agreement Concerning ZoMaxx

I note your comments with respect to Birmingham's case before Judge Scheindlin in the District Court. It is our view that we have properly instituted an action against the relevant party for breach of the relevant agreement.



William F. Cavanaugh, Jr. January 18, 2008 Page 2

It is unclear whether your reference to a discussion to resolve "the disputes" was intended to include a dispute with respect to the claim stated in the Complaint. As the claim arises out of the Keep Well Agreement, there are no agreed procedures for such a discussion. Birmingham is willing to enter into a good-faith negotiations with Abbott in an attempt to resolve its claim, provided that the parties can conclude an agreement as to confidentiality and exclusion from evidence that would also establish that any such discussions were without prejudice to Birmingham's position that its claim against Abbott is not subject to the ADR procedures of the Funding Agreement. Please let me know if Abbott will enter into such an agreement.

### ALVE's Purported Dispute with Birmingham Concerning ZoMaxx

Your letter, while for the first time purporting to describe a dispute between Birmingham and ALVE, fails to make clear how Birmingham's complaint against Abbott for breach of the Keep Well Agreement gave rise to a bona fide dispute between Birmingham and ALVE. Thus, in response to Mr. Commandeur's voicemail question to me of yesterday, we do not view ALVE as having notified us of a claim subject to the ADR provisions of the Funding Agreement.

Birmingham is nevertheless willing to discuss the matter further, and to engage in negotiations with ALVE with a view toward resolving any differences. Birmingham has consistently sought a negotiated, commercial resolution of its concerns, and takes the same attitude here.

Very truly yours,

Daniel C. Malone